

CONFIDENTIAL

Attachment C  
Reoccurrence of Malignant Breast Disease

Core Gel Study of the Safety and Effectiveness of the Mentor Round Gel-Filled Mammary Prosthesis  
in Patients Who Are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision  
Complications/Mammogram Result for the Five Patients with a diagnosis of Malignancy in the Breast Prior to Implantation  
who had a Reoccurrence of Malignant Breast Disease

Date of Explant	Patient ID	Breast	Complications		AE Onset Date	Day from Original Surgery	Severity	Causality	Outcome	First
			AE Onset Date	Complication Event						
08/22/01		LEFT	11/16/01	Other: Recurrent Breast Cancer	11/16/01	302	SEVERE	OTHER	ONGOING	
		RIGHT	06/05/01	Infection	06/05/01	138	SEVERE	UNKNOWN	RESOLVED	
08/22/01			07/17/01	Baker III Capsular Contracture	07/17/01	180	SEVERE	UNKNOWN	RESOLVED	
08/22/01				Implant Malposition/Displacement	07/17/01	180	MILD	PROCEDURE	RESOLVED	
08/22/01				wrinkling	07/17/01	180	MODERATE	RELATED PROCEDURE	RESOLVED	
08/22/01			08/21/01	Extrusion	08/21/01	215	MODERATE	RELATED UNKNOWN	RESOLVED	
		FT N/A RIGHT	04/27/02	Other: Recurrent Breast Cancer	04/27/02	534	SEVERE	OTHER	DEATH	
		LEFT	02/27/02	Infection	02/27/02	448	MODERATE	UNKNOWN	RESOLVED	
				Other: Recurrent Breast Cancer	02/27/02	448	MODERATE	UNKNOWN	DEATH	
		LEFT								
		RIGHT	03/26/02	Other: Recurrent Breast Cancer	03/26/02	273	SEVERE SEVERE	OTHER OTHER	ONGOING ONGOING	
		LEFT	03/21/02	Other: Recurrent Breast Cancer	03/21/02	112	SEVERE	OTHER	RESOLVED	
		RIGHT	03/15/02	Other: Recurrent Breast Cancer	03/15/02	106	SEVERE	OTHER	RESOLVED	

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Mammography Results

Patient ID	Breast	Visit	Date of Mammogram	Day from Original Surgery to Mam date	Mammogram Result	Abnormality	Biopsy Result
	LEFT						
	RIGHT						
	LEFT	BASELINE	09/15/00	-55	BIRADS 2		
	N/A						
	RIGHT	BASELINE	09/15/00	-55	BIRADS 1		
	LEFT						
	LEFT	BASELINE	02/15/01	-131	BIRADS 1		
		1 YEAR VISIT	03/15/02	262	BIRADS 3		POSITIVE
	RIGHT	BASELINE	02/15/01	262	BIRADS 1		
		1 YEAR VISIT	03/15/02	262	BIRADS 5	LUMP CALCIFICAT ION	POSITIVE
	LEFT						
	RIGHT						

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